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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,715	01/12/2000	CLARE PASSMORE	6442/60557	7077

7590 10/18/2004  
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NEW YORK, NY 10036

EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# **Notice of Allowability** (Supplemental)

Application No.

09/423,715

Examiner

Gregory W Mitchell

Applicant(s)

PASSMORE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed March 10, 2004.
2. ☒ The allowed claim(s) is/are 1-9, 12-19, 23, 25-27, 29-32 and 34-37.
3. ☒ The drawings filed on 12 November 1999 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## **Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-9, 11-20, 25-32 and 34-37 are pending. The Amendment filed March 10, 2004 cancelled claim 33, and amended claims 1, 13, 14, 16, 17, 23, 31, 32, 35, 36, and 37.

### ***EXAMINER'S AMENDMENT***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jay Maioli on 06/21/04.

The application has been amended as follows:

1) In claim 1, delete the last paragraph, i.e., the text of "wherein one of the first or the second pharmacologically active agent ... or choline salicylate", **AND** delete the phrase ", and" in line 21.

2) Following the phrase "at least one compatible emulsifying agent," in claim 1, insert the following,

"wherein the first pharmacologically active agent is selected from the group consisting of chlorocresol, chlorbutanol, methyl nicotinate, triprolidine, promethazine, trimeprazine, sulfiram, oxybutynin, testosterone enanthate, and choline salicylate,

wherein the second pharmacologically active agent is selected from the group consisting of chlorocresol, trimeprazine, choline salicylate, methyl nicotinate, ibuprofen,

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ketoprofen, fenoprofen, flurbiprofen, etodolac, fentanyl, econazole, ketoconazole, mupirocin, chlorbutanol, clindamycin, iodine, oxybutynin, tetramisole, triprolidine, promethazine, and propranolol, in which the at least two pharmacologically active agents are structurally and/or pharmacologically diverse,”.

3) In claim 23, delete the following (lines 24-31), “and wherein one of the first or the second pharmacologically active agent is triclosan ... or choline salicylate,”.

4) Following the phrase “and at least one compatible emulsifying agent” in claim 23 (line 18), insert the following,

“wherein the first pharmacologically active agent is selected from the group consisting of triclosan, chlorocresol, chlorbutanol, methyl nicotinate, triprolidine, promethazine, trimeprazine, sulfiram, oxybutynin, testosterone enanthate, and choline salicylate,

wherein the second pharmacologically active agent is selected from the group consisting of triclosan, chlorocresol, capsaicin, trimeprazine, choline salicylate, methyl nicotinate, ibuprofen, ketoprofen, fenoprofen, flurbiprofen, etodolac, fentanyl, econazole, ketoconazole, mupirocin, chlorbutanol, clindamycin, iodine, oxybutynin, tetramisole, triprolidine, promethazine, and propranolol, in which the at least two pharmacologically active agents are structurally and/or pharmacologically diverse, and”.

5) Cancel claims 11, 20, 28.

6) Under the title page on page 1 of the specification, insert the following, “This Application is a national stage entry of PCT/IE98/00036.”

### ***REASONS FOR ALLOWANCE***

The following is an examiner's statement of reasons for allowance:

Claims 1-9, 12-19, 23, 25-27, 29-32, 34-37 are allowable over the prior art, as the prior art neither anticipates nor renders obvious the instant composition.

The closest prior art is USPN 5,854,246, which teaches oil-in-water emulsions containing ketoconazole, and other active ingredients such as chlorocresol. However, the reference fails to teach the active ingredients in the discontinuous phase (oil) and fails to teach the eutectic mixture. In fact, aside from not teaching eutectic mixtures, both ketoconazole and the chlorocresol of the reference are dissolved in the aqueous phase and not the oily discontinuous phase. Furthermore, the process conditions of the reference do not permit direct contact between the preservatives, i.e., chlorocresol, and ketoconazole, and, without that direct contact, a eutectic mixture of ketoconazole and a preservative will not occur.

The Amendment filed March 10, 2004 is sufficient to overcome the 35 U.S.C. 112 rejections in the previous Office Action.

The Examiner's Amendment in combination with the Arguments filed March 10, 2004, is sufficient to overcome the 35 U.S.C. 103 rejection of the previous Office Action.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

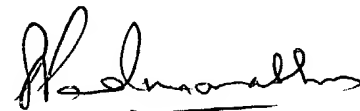
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



**SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER**